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Steve Mitchell

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65901

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MEDTRONIC

Attn: Noreen Johnson - IP Legal Department

2600 Sofamor Danek Drive

Memphis, TN 38132

EXAMINER

HOFFMAN, MARY C

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

03/05/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Claim Objections

Claims 43-56 and 82 are objected to because of the following informalities: In claim 43, it appears Applicant inadvertently used the term "the gap" in line 13 instead of the term "the notch" which has proper antecedent basis in line 6. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the limitation "the enlarged first end" in line 10. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 9, 12-16 and 20-24 rejected under 35 U.S.C. 102(e) as being anticipated by Zucherman et al. (U.S. Patent App. No 2002/0029039).

Zuckerman discloses an implant comprising a body; at least one hook extending from the body and adapted to allow the body to engage a SI vertebra; a brace extending from the body and including an elongated shape with a major axis and a minor axis, wherein the brace has a distal end on the major axis adapted for contacting an inferior surface of a spinous process of the a L5 vertebra during extension of the spine; and a device that can secure the brace to the body (see e.g. FIGS. 131, 137, 141). The implant is comprised of titanium. The device can secure the brace to the body in a plurality of positions. The distal end is bulbous. The distal end is round. The distal end provides a surface which is at an angle to a beam of the brace, which surface is adapted to engage the L5 vertebra. The distal end includes a convex surface that is adapted to engage a spinous process of the L5 vertebra to spread the load between the distal end and the spinous process. The brace includes an elongated aperture and the device extends through the aperture and can be secured to the aperture in a plurality of positions in order to position the brace relative to the body in a plurality of positions. The body includes a first portion and a second portion with a beam platform located between the first and second portions and the beam platform spaced from the first and second portions in order to space the brace from the first and second portions. The hook

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extends from the first portion and another hook extends from the second portion. The device extends from the platform.

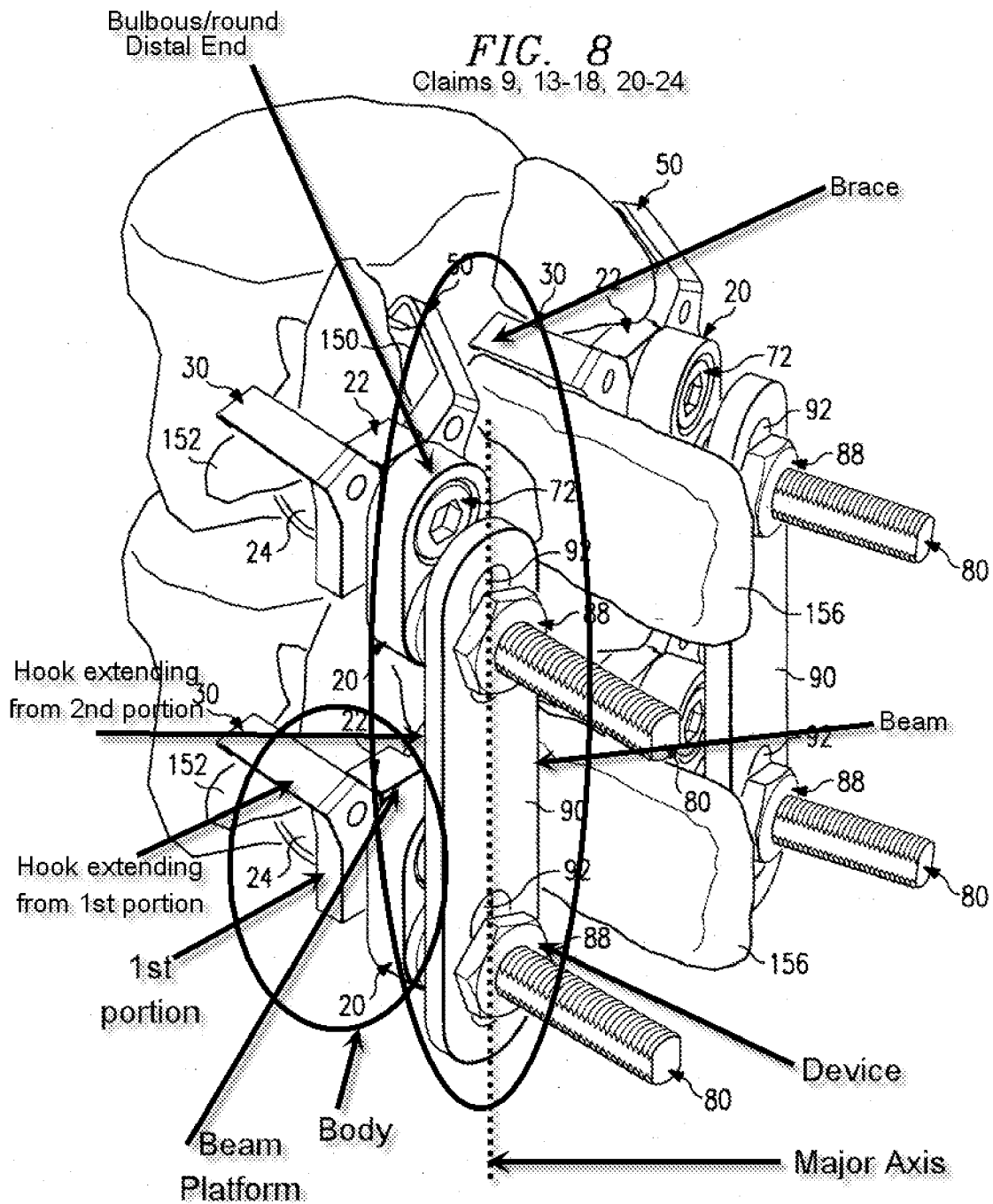
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9, 13-16, 20-24 and 82 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (U.S. Patent No. 5,415,659).

Lee et al. discloses the claimed invention. The rejection is illustrated in the below marked-up figure. The claims features are labeled in the below marked-up figures.

CLAIMS 9, 13-18 and 20-24

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (U.S. Patent No. 5,415,659).

Lee et al. disclose the claimed invention except for the implant being made from a material such as polyetheretherketone, polyaryletheretherketone, and polyetherketoneketone, polyetherketoneetherketoneketone, polyetheretherketoneketone, polyketone, polyetherketone, or titanium.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct at least a part of the device of Lee et al. from a material such as polyetheretherketone, polyaryletheretherketone, polyetherketoneketone, polyetherketoneetherketoneketone, polyetheretherketoneketone, polyketone, polyetherketone, or titanium, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zucherman et al. (U.S. Patent App. No 2002/0029039).

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Zucherman et al. disclose the claimed invention except for the implant being made from a material such as polyetheretherketone, polyaryletheretherketone, and polyetherketoneketone, polyetherketoneetherketoneketone, polyetheretherketoneketone, polyketone, polyetherketone

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct at least a part of the device of Zucherman et al. from a material such as polyetheretherketone, polyaryletheretherketone, polyetherketoneketone, polyetherketoneetherketoneketone, polyetheretherketoneketone, polyketone, polyetherketone, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Allowable Subject Matter

Claims 26-42, 58-64, 66-69, 77 and 83-84 are allowed.

Claims 43-56 and 85 objected to for a minor claim formality but are otherwise allowable.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed 12/02/2008 have been fully considered but they are not persuasive with regard to independent claim 9 and dependent claims thereof.

With regard the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Lee, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference “teach” what the subject patent teaches, but rather it is only necessary that the claims under attack “read on” something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Claim 9 does not require that the brace be adapted for contacting the inferior surface while implanted such that the at least one hook engages a S1 vertebra, therefore, the Lee device and the Zucherman device are capable of performing the claimed function of being adapted to contact the inferior surface.

The rejections are deemed proper.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARY HOFFMAN whose telephone number is (571)272-5566. The examiner can normally be reached on Monday-Thursday 10:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary C. Hoffman/
Examiner, Art Unit 3733
/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733